



IMAGE

55099-A-PCT-US/JPW/AJM/AJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ilya Trakht

Serial No.: 09/664,485

Examiner: Laurie A. Scheiner

Filed: September 18, 2000

Art Unit: 1648

For: DEVELOPMENT OF HUMAN MONOCLONAL ANTIBODIES AND USES THEREOF

1185 Avenue of the Americas
New York, New York 10036
January 19, 2005

Director of the U.S. Patent
and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PETITION UNDER 37 C.F.R. §1.181(a)
TO WITHDRAW HOLDING OF ABANDONMENT

This Petition is submitted under 37 C.F.R. §1.181(a) to request withdrawal of the holding of abandonment set forth in the Notice of Abandonment issued December 9, 2004 in connection with the above-identified application. A response to the December 9, 2004 Notice is due February 9, 2005. Accordingly, this Petition is being timely filed.

The December 9, 2004 Notice states that the subject application was abandoned for applicant's alleged failure to timely file a proper reply to the Office Action mailed May 28, 2004. A copy of the December 9, 2004 Notice is attached hereto as **Exhibit X**.

In response, applicant notes that he filed an Amendment in response to the May 28, 2004 Office Action on August 30, 2004. Applicant attaches hereto as **Exhibit Y** a copy of the August 30, 2004 Amendment, including Supplemental Information Disclosure Statement and Exhibits A-C and 1-12. A response to the May 28, 2004 Office Action was due August 30, 2004, since August 28, 2004 fell on a Saturday, and a response filed Monday, August 30, 2004 was to be considered timely. Accordingly, the August 30, 2004 Amendment was timely filed.

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Filed: September 18, 2000
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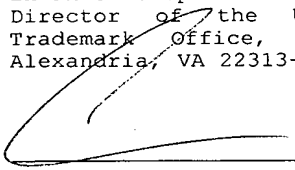
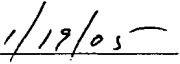
Applicant also attaches hereto as **Exhibit Z** a copy of the postcard which accompanied the August 30, 2004 Amendment and which was returned to applicant's undersigned attorney by the Patent Office. The postcard confirms receipt of the August 30, 2004 Amendment by the Patent Office on September 1, 2004, as evidenced by the Patent Office's stamp bearing that date.

In view of the evidence submitted herewith, it is clear that applicant filed a timely response to the May 28, 2004 Office Action, and that this response was received by the Patent Office. Applicant therefore respectfully requests that the holding of abandonment set forth in the December 9, 2004 Notice of Abandonment be withdrawn, and the subject application proceed to examination.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

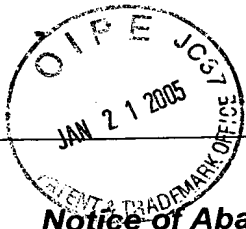
No fee is deemed necessary in connection with the filing of this Petition. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

| | |
|---|---|
| I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Director of the U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. | |
|  Alan J. Morrison Reg. No. 37,399 |  Date 11/19/05 |

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

EXHIBIT X



55049-A-YCT-US

JPW

Notice of Abandonment**Application No.**

09/664,485

Examiner

Laurie A. Scheiner

Applicant(s)

TRAKHT, ILYA

Art Unit


1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

Petition to Revive: 2/9/05

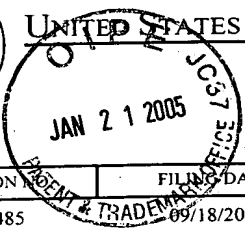
1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 28 May 2004.
 - (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☒ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$ _____ is insufficient. A balance of \$ _____ is due.
The issue fee required by 37 CFR 1.18 is \$ _____. The publication fee, if required by 37 CFR 1.18(d), is \$ _____.
BSC
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:


Laurie A. Scheiner
Primary Examiner
Art Unit: 1648

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.



UNITED STATES PATENT AND TRADEMARK OFFICE



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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|------------------------|------------------|
| 09/664,485 | 09/18/2000 | Ilya Trakht | 55099-A-PCT-US/JPW/GJC | 4698 |

7590

12/09/2004

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

SCHEINER, LAURIE A

ART UNIT PAPER NUMBER

1648

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

EXHIBIT Y



55099-A-PCT-US/JPW/AJM/AJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ilya Trakht
Serial No.: 09/664,485 Examiner: Shanon Foley
Filed: September 18, 2000 Art Unit: 1648
For: DEVELOPMENT OF HUMAN MONOCLONAL ANTIBODIES AND USES
THEREOF

1185 Avenue of the Americas
New York, New York 10036
August 30, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

AMENDMENT IN RESPONSE TO MAY 28, 2004 OFFICE ACTION
AND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

This Amendment is submitted in response to the May 28, 2004 Office Action issued by the United States Patent and Trademark Office in connection with the above-identified application. A response to the May 28, 2004 Office Action is due August 28, 2004. However, since August 28, 2004 falls on a Saturday, a response filed Monday, August 30, 2004 is to be considered timely. Accordingly, this Amendment is being timely filed.

Please amend the subject application as follows:

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Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the specification:

Listing of Claims:

1-78. (Canceled)

79. (Previously Presented) A composition which comprises a suitable carrier and an effective amount of a monoclonal antibody, which monoclonal antibody is produced by a method comprising:

- (a) fusing a lymphoid cell capable of producing antibody with a trioma cell which does not produce any antibody and is obtained by fusing a heteromyeloma cell which does not produce any antibody with a human lymphoid cell so as to thereby form tetroma cells;
- (b) incubating the tetroma cells formed in step (a) under conditions permissive for the production of antibody by the tetroma cells, so as to thereby produce the monoclonal antibody; and
- (c) recovering the monoclonal antibody so produced.

80. (Previously Presented) The composition of claim 79, wherein the monoclonal antibody is specific for an antigen associated with a condition in a subject.

81. (Previously Presented) The composition of claim 80, wherein the condition is cancer and the amount of monoclonal antibody is sufficient to inhibit the growth of or eliminate the cancer.

82. (Previously Presented) The composition of claim 81, wherein the cancer is breast cancer, thyroid cancer or prostate cancer.

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83-88. (Canceled)

89. (Previously Presented) The composition of claim 80, wherein the monoclonal antibody is coupled to an effector molecule.
90. (Previously Presented) The composition of claim 89, wherein the effector molecule is a cytotoxic agent, drug, enzyme, dye, or radioisotope.
91. (Previously Presented) The composition of claim 80, wherein the monoclonal antibody is coupled to a carrier.
92. (Previously Presented) The composition of claim 91, wherein the carrier is a liposome.
93. (Previously Presented) A method of treating a condition in a subject comprising administering to the subject an amount of the composition of claim 80 effective to bind the antigen associated with the condition so as to treat the condition in the subject.
94. (Previously Presented) A method of preventing a condition in a subject comprising administering to the subject an amount of the composition of claim 80 effective to bind the antigen associated with the condition so as to prevent the condition in the subject.
95. (Previously Presented) The method of claim 94, wherein the subject previously exhibited the condition.
96. (Previously Presented) The method of claim 93 or 94 wherein the condition is associated with a cancer, a tumor, a toxin, an infectious agent, an enzyme dysfunction, a hormone dysfunction, an autoimmune disease, an immune dysfunction, a viral antigen, a bacterial antigen, a eukaryotic antigen, or rejection of a transplanted tissue.

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97. (Canceled)

98. (Previously Presented) The method of claim 96, wherein the cancer is breast cancer.

99-100. (Canceled)

101. (Previously Presented) The method of claim 96, wherein the tumor is benign.

102-105. (Canceled)

106. (Previously Presented) The composition of claim 79, wherein the heteromyeloma cell is the cell designated B6B11 (ATCC accession number HB-12481).

107. (Previously Presented) The composition of claim 79, wherein the heteromyeloma cell is a B6B11-like cell.

108. (Previously Presented) The composition of claim 79, wherein the human lymphoid cell is a myeloma cell.

109. (Previously Presented) The composition of claim 79, wherein the human lymphoid cell is a splenocyte or a lymph node cell.

110. (Previously Presented) The composition of claim 79, wherein the trioma cell is the cell designated MFP-2 (ATCC accession number HB-12482).

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REMARKS

Claims 79-110 are pending in the subject application. By this Amendment, applicant has canceled non-elected claims 83-88, 97, 99, 100 and 102-105 without disclaimer or prejudice to applicant's right to pursue the subject matter of these claims at a later date in a continuing application. Accordingly, upon entry of this Amendment, claims 79-82, 89-96, 98, 101 and 106-110 will be pending and under examination.

In view of the arguments set forth below, applicant submits that the Examiner's rejections made in the May 28, 2004 Office Action have been overcome. Applicant therefore respectfully requests that the Examiner reconsider and withdraw these rejections.

The Claimed Invention

This invention provides compositions comprising a human monoclonal antibody and a carrier. In a preferred embodiment of this invention, the monoclonal antibody is specific for an antigen associated with cancer, and the amount of the monoclonal antibody in the composition is sufficient to inhibit the growth of or eliminate the cancer. The invention provides methods for treating or preventing a condition in a subject comprising administering to the subject an amount of the claimed composition effective to bind an antigen associated with the condition. In a preferred embodiment, the condition is cancer.

Restrictions/Election

The Examiner acknowledged applicant's November 6, 2003 election with traverse of Group I, claims 79-82, 89-96, 98, 101 and 106-110, and applicant's species election. The Examiner noted that traversal was on the ground(s) that there would not be a serious burden on the Examiner if restriction (and species) were not required. The Examiner stated that applicant's arguments have been considered but that they have not been found persuasive

Applicant: Ilya Itrakht
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because a serious search burden does in fact exist. Accordingly, the Examiner stated that the requirement is still deemed proper and is therefore made FINAL.

In response, applicants have canceled, without disclaimer or prejudice, claims 83-88, 97, 99, 100 and 102-105 which had been withdrawn from consideration by the Examiner as being drawn to a non-elected invention.

Double Patenting Rejections

The Examiner rejected claims 79-82 and 106-110 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-9 of U.S. Patent No. 6,197,582 ("582 Patent"). The Examiner stated that although the conflicting claims are not identical, they are not patentably distinct from each other because the antibodies of the instant compositions are secreted from the cells (trioma and tetroma) of the patent.

In response, applicants respectfully traverse this rejection.

As alluded to by the Examiner, claims 79-82 and 106-110 are directed to compositions comprising a monoclonal antibody. However, contrary to the Examiner's statement, applicant notes that this antibody is not secreted by a trioma cell. For the Examiner's convenience, applicant attaches hereto as **Exhibit A** a copy of the issued claims in the '582 Patent. Applicant respectfully points out to the Examiner that claims 1-4 and 8 of this patent are directed to "[a] trioma cell which does not produce any antibody." Thus, applicant submits that a composition comprising an antibody cannot be obvious over a trioma cell which does not produce any antibody. Applicant maintains, therefore, that the pending claims of the present application are patentably distinct from claims 1-4 and 8 of the '582 Patent.

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Applicant notes that claims 5-7 and 9 of the '582 Patent are directed to a tetroma cell which is capable of producing a monoclonal antibody. Applicant maintains that the claimed tetroma does not render obvious the instant *composition*, since no motive to combine an antibody with a carrier is present from the claims, and likewise, no reasonable expectation of success is present from the claims. Thus, applicant maintains that all pending claims of the present application are patentably distinct from claims 1-9 of the '582 Patent.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claim 107 under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated that claim 107 is vague and indefinite since one cannot determine that which is intended by the recitation of "B6B11-like cell" since B6B11 is a specific heteromyeloma cell deposited under Accession No. HB-12481.

In response, applicants respectfully traverse this rejection.

Applicant notes that in construing claim language, claims must be read in light of the specification. In this regard, applicant notes that a "B6B11-like" cell is defined in the specification at page 23, lines 29-31 as a hybrid cell produced by the fusion of a mouse myeloma 653-related cell and a human myeloma RPMI 8226-related cell. In addition, the specification at, *inter alia*, page 30, lines 29-32 and page 43, lines 1-4 provides an example of the fusion of the commercially available human myeloma cell line, RPMI 8226, and the mouse myeloma line, X63.Ag8.653, to produce G-418-resistant clones. One of these clones was designated B6B11. The specification states further at page 23, lines 33-36 that B6B11-like cells share functional properties and characteristics with B6B11 heteromyeloma cells. Applicant notes that the specification describes various functional properties and

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characteristics of B6B11 cells, including their G-418-resistant, 8-Ag-resistant and HAT-sensitive phenotypes (see specification at, *inter alia*, page 30, lines 32-36); their non-production of immunoglobulins or heavy or light chains (page 36, lines 15-18); and their ability to fuse with human lymphocytes to produce easily cloned hybrids which stably secrete immunoglobulins (page 30, lines 14-19 and 36-38; page 32, Table 1; page 36, lines 18-33; and page 44, lines 13-16).

In view of the details provided in the specification as to the definition and characteristics of a "B6B11-like" cell, applicant maintains that one skilled in the art would readily be able to identify cell lines related to the mouse myeloma 653 and human myeloma RPMI 8226 cell lines. The skilled artisan would also be able to fuse such cell lines and screen for a B6B11-like cell with the functional properties and characteristics described in the specification. Thus, applicants maintain that the disclosures in the specification make the meaning of the term "B6B11-like cell" clear to a person of ordinary skill in the art. Applicant respectfully submits, therefore, that the recitation of "B6B11-like cell" in claim 107 does not render the claim indefinite.

Rejections under 35 U.S.C. §112, First Paragraph

The Examiner objected to the specification under 35 U.S.C. §112, first paragraph, as allegedly failing to provide an enabling disclosure.

The Examiner stated that it is apparent that the trioma cell ATCC HB 12482 is required to practice the invention as set forth in instant claim 110. The Examiner also stated that, similarly, the heteromyeloma cell ATCC HB 12481 is required to practice the invention as set forth by instant claim 106. The Examiner further stated that since the respective cells are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The Examiner also stated that the

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claimed cells are not fully disclosed, nor have they been shown to be publicly known and freely available. The Examiner additionally stated that the enablement requirements of 35 U.S.C. §112 may be satisfied by deposits of the above-mentioned cells. The Examiner further stated that the specification does not disclose a repeatable process to obtain the cells. The Examiner also stated that, accordingly, it is deemed that a deposit of these cells should have been made in accordance with 37 CFR 1.801-1.809.

The Examiner noted that applicant has deposited two cells under ATCC Accession Nos. HB 12481 and HB 12482, but that there is no indication in the specification as to public availability. The Examiner stated that if the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney or record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

The Examiner also stated that claims 106 and 110 are rejected under 35 U.S.C. §112, first paragraph, for the reasons set forth above in the objection to the specification.

In response, applicants affirm that the B6B11 heteromyeloma and MFP-2 trioma cells disclosed in the subject invention were deposited on March 17, 1998, pursuant to the Budapest Treaty, with the Patent Culture Depository of the American Type Culture Collection (ATCC) under ATCC Accession Nos. HB-12481 (B6B11 heteromyeloma) and HB-12482 (MFP-2 trioma). For the Examiner's convenience, applicant attaches hereto as **Exhibit B** a copy of the April 6, 1998 Budapest Treaty Deposit Receipt and Viability Statement for the B6B11 heteromyeloma and MFP-2 trioma cells. In accordance with the requirements of C.F.R. 1.808, applicant's undersigned attorneys state that the deposits of the B6B11

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heteromyeloma and MFP-2 trioma cell lines were made under the terms of the Budapest Treaty, and that all restrictions on the availability to the public of the materials deposited under ATCC Nos. HB-12481 and HB-12482 will be irrevocably removed upon the grant of a patent from the subject application. Notwithstanding the above remarks, applicant in no way concedes the correctness of the Examiner's remarks which form the basis of this rejection.

In view of the foregoing, applicant requests that the Examiner withdraw the rejection of claims 106 and 110 under 35 U.S.C. §112, first paragraph.

Conclusion

In view of the remarks made hereinabove, applicant respectfully requests that the Examiner reconsider and withdraw the claim rejections set forth in the May 28, 2004 Office Action, and earnestly solicits allowance of all claims pending in the subject application.

Applicant: ~~Ashton Delauney~~
Serial No.: 09/664,485
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Supplemental Information Disclosure Statement

Applicant notes that on the PTO-1449 form returned by the Examiner with the May 28, 2004 Office Action, listed patent documents were initialed to indicate they had been considered by the Examiner but lines were drawn through the non-patent references, suggesting that these had not been considered. In a June 7, 2004 telephone conference with Ashton Delauney, Esq. of the undersigned attorney's office, the Examiner explained that whereas she had been able to access the cited patent documents online, she had been unable to locate copies of any of the non-patent references listed on the PTO-1449 form in the August 23, 2001 Information Disclosure Statement. Applicant notes that, pursuant to 37 C.F.R. §1.98(d), copies of these non-patent references had not been submitted to the Patent Office in the August 23, 2001 Information Disclosure Statement since copies had previously been submitted in a November 20, 1998 Information Disclosure Statement filed in connection with U.S. Serial No. 09/040,833, now U.S. Patent No. 6,197,582, on which the present application relies for an earlier filing date under 35 U.S.C. §120. The Examiner requested during the June 7, 2004 telephone conference that applicant resubmit copies of these non-patent references together with his response to the pending Office Action.

In response to the Examiner's request and in accordance with his duty of disclosure under 37 C.F.R. §1.56, applicant directs the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit C**) and attached hereto as **Exhibits 1-12**:

1. Brodin T., Olsson L., Sjorgen H. (1983) Cloning of human hybridoma, myeloma, and lymphoma cell lines using enriched human monocytes as feeder layer, J. Immunol. Meth. 60: 1-7 (**Exhibit 1**);
2. Goldman-Leikin, R.E., Salawen, H.R., Herst, C.V., Variakojis, D., Bian, M.L., Le Beau, M.M., Selvanayagen, P.,

Applicant: Ilya Ilyan
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- Marder R., Anderson, R., Weitzman, S., Rosen, S.T. (1989) Characterization of a novel myeloma line MM-I, J. Lab. Clin. Med. 113: 335-345 (**Exhibit 2**);
3. Kozbor, D., Roder, J.C. (1981) Requirements for the establishment of high titered human monoclonal antibodies against tetanus toxoid using the Epstein-Barr virus technique, J. Immunol. 127: 1275-1280 (**Exhibit 3**);
 4. Kozbor, D., Tripputi, P., Roder, J.C., Croce, C.M. (1984) A human hybrid myeloma for production of human monoclonal antibodies, J. Immunol. 133: 3001-3005 (**Exhibit 4**);
 5. Levy, R., Miller, R.A. (1983) Tumor therapy with monoclonal antibodies, Fed. Proc. 42: 2650-2656 (**Exhibit 5**);
 6. Nilsson, K., Ponten, J. (1975) Classification and biological nature of established human hematopoietic cell lines, Int. J. Cancer 15: 321-341 (**Exhibit 6**);
 7. Oestberg, L., Pursch, E. (1983) Human x (mouse x human) hybridomas stably producing human antibodies, Hybridoma 2: 361-367 (**Exhibit 7**);
 8. Posner, M.R., Schlossman, S.F., Lazarus, H. (1983) Novel approach to the construction of human "myeloma analogues" for the production of human monoclonal antibodies, Hybridoma 2: 369-381 (**Exhibit 8**);
 9. Reading, C.L. (1982) Theory and methods for immunization in culture and monoclonal antibody production, J. Immunol. 53: 261-291 (**Exhibit 9**);
 10. Raison, R.L., Walker, K.Z., Halnan, C.R.E., Briscoe, D., Basten, A. (1982) Loss of secretion in mouse-human hybrids need not be due to the loss of a structural gene, J. Exp.

Applicant: Liya Liang
Serial No.: 09/664,485
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Med. 156: 1380-1389 (**Exhibit 10**);

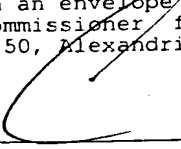
11. Teng, N.N.H., Lam, K.S., Riera, F.C., Kaplan, H.S. (1993) Construction and testing of mouse-human heteromyelomas for human monoclonal antibody production, Proc. Natl. Acad. Sci. (U.S.A.) 80: 7308-7311 (**Exhibit 11**); and
12. Weiss, M.C., Green, H. (1967) Human mouse hybrid cell lines containing partial complements of human chromosomes and functioning human genes, Proc. Natl. Acad. Sci. (U.S.A.) 58: 1104-1111 (**Exhibit 12**).

The Examiner is respectfully requested to make these references of record in the present application by initialing and returning a copy of the enclosed Form PTO-1449.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

| | |
|---|---------|
| I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. | |
|  | 8/30/01 |
| Alan J. Morrison Reg. No. 37,399 | Date |

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400



What is claimed is:

1. A trioma cell which does not produce any antibody obtained by fusing a heteromyeloma cell which does not produce any antibody with a human lymphoid cell, wherein the heteromyeloma cell is designated B6B11 (ATCC Designation number HB-12481).
2. The trioma cell of claim 1, wherein the human lymphoid cell is a myeloma cell.
3. The trioma cell of claim 1, wherein the human lymphoid cell is a splenocyte or a lymph node cell.
4. The trioma cell of claim 1, wherein the trioma cell is designated MFP-2 (ATCC Designation number HB-12482).
5. A tetroma cell capable of producing a monoclonal antibody having specific binding affinity for an antigen obtained by fusing the trioma cell of claim 1 with a human lymphoid cell capable of producing antibody having specific binding affinity for the antigen.
6. The tetroma cell of claim 5, wherein the human lymphoid cell is selected from the group consisting of a peripheral blood lymphocyte, a splenocyte, a lymph node cell, a B cell, a T cell, a tonsil gland lymphocyte, a monocyte, a macrophage, an erythroblastoid cell and a Peyer's patch cell.
7. The tetroma cell of claim 5, wherein the antigen is selected from the group consisting of a tumor-associated antigen, a cell specific antigen, a tissue-specific antigen, an enzyme, a nucleic acid, an immunoglobulin, a toxin, a viral antigen, a bacterial antigen and a eukaryotic antigen.
8. A trioma cell generated by a method comprising:
 - (a) fusing a heteromyeloma cell which does not produce antibody with a human lymphoid cell thereby forming a trioma cell;
 - (b) incubating the trioma cell formed in step (a) under conditions permissive to the production of antibody by the trioma cell; and
 - (c) selecting a trioma cell that does not produce antibody,wherein the heteromyeloma cell of step (a) is designated B6B11 (ATCC Designation number HB-12481).
9. A tetroma cell generated by a method comprising:
 - (a) fusing the trioma cell of claim 1 with a human lymphoid cell thereby forming a tetroma cell;
 - (b) incubating the tetroma cell formed in step (a) under conditions permissive to the production of antibody by the tetroma cell; and
 - (c) selecting a tetroma cell capable of producing a monoclonal antibody.

ATCC

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Cooper & Dunham, LLP
Attn: John P. White
1185 Avenue of the Americas
New York, NY 10036

Deposited on Behalf of: The Trustees of Columbia University in the City of New York
(Ref. Docket 55099/JPW/SBS)

Identification Reference by Depositor:

ATCC Designation

Human hybridoma fusion partner cell line heteromyloma B6B11
Human hybridoma fusion partner cell line trioma MFP-2

HB-12481
HB-12482

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above. The deposits were received March 17, 1998 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested April 6, 1998. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara M. Hailey
Barbara M. Hailey, Administrator, Patent Depository

Date: April 6, 1998

cc: Steven B. Stein

BEST AVAILABLE COPY

EXHIBIT Z

FILE

Applicant Ilya Trakht
Client Columbia (0575) File No. 55099-A-PCT-US Atty. JPW/AJM/AJD
Date August 30, 2004

Kindly acknowledge receipt of the accompanying

Amendment In Response To May 28, 2004 Office Action And Supplemental Information Disclosure Statement in connection with Ilya Trakht, DEVELOPMENT OF HUMAN MONOCLONAL ANTIBODIES AND USES THEREOF, U.S. Serial No. 09/664,485, filed September 18, 2000, including copy of issued claims in U.S. Patent No. 6,197,582 (Exhibit A), copy of ATCC Deposit Receipt (Exhibit B), PTO Form 1449 (Exhibit C), copies of references (Exhibits 1-12), and Certificate of Mailing dated August 30, 2004

Due Date: August 30, 2004

by placing your receiving date stamp hereon and returning to us.

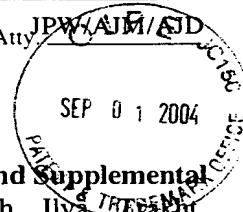
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